UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/165,546	10/02/98	ALEXANDER K	LUD5466.4-JE

EXAMINER
WILSON, M

ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 03/16/00

HM12/0316
FULBRIGHT & JAWORSKI L.L.P.
666 FIFTH AVENUE
NEW YORK NY 10103-3198

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No. 09/165,546	Applic[illegible](s) Alexander et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-73* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-73* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-9, 10, 14, 15, 19-31, 36-38, 40, 55-60, 63 and 68-73 drawn to polypeptides which bind MHC-Class II HLA-DR53 molecules, HLA-DR53/polypeptide complexes, a mixture of polypeptides, methods of stimulating proliferation of T helper cells, treating cancer and preventing cancer using polypeptides which bind MHC-Class II HLA-DR53 molecules, a complex of MHC-Class II molecule HLA-DR53 and a polypeptide, classified in class 530, subclass 350.

II. Claim 6, drawn to a cytolytic T cell, classified in class 435, subclass 325.

III. Claims 11-13, 16-18, 39, 61, 62 and 64-67 drawn to nucleic acids, vectors encoding polypeptides which bind MHC-Class II HLA-DR53 molecules, cells comprising the nucleic acids and vectors and a method of treating cancer using a nucleic acid sequence encoding a polypeptide which bind MHC-Class II HLA-DR53, classified in class 536, subclass 23.1.

IV. Claims 32-34 and 41, drawn to methods of stimulating proliferation of T helper cells using transfected cells and a method of treating cancer using recombinant cells encoding polypeptides which bind MHC-Class II HLA-DR53, classified in class 424, subclass 93.1.

V. Claim 35, drawn to a method of treating cancer using an antibody, classified in class 424, subclass 130.1.

VI. Claims 42, 43 and 47-54 drawn to a method of screening cancer by assaying protein complexes or T helper cells, classified in various classes, subclasses.

VII. Claims 44-46, drawn to methods of detecting cancer using transfected cells *in vitro*, classified in class 435, subclass 325.

2. The inventions are distinct, each from the other because of the following reasons: Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Groups I and II are patentably distinct because the polypeptide can be used to isolate antibodies while the cytolytic T cell (CTL) can be used in *in vitro* assays to detect cancer as in Group XIII. The protocols and reagents required to use polypeptides are materially distinct and separate than those required to use CTL. The polypeptides do not require the CTL and the CTL do not require the polypeptides.

Groups I and III are patentably distinct because the polypeptide can be used to isolate antibodies while the nucleic acids, vectors and recombinant cells can be used to make protein. The protocols and reagents required to use polypeptides are materially distinct and separate than those required to use nucleic acids, vectors and recombinant cells. The polypeptides do not

require the nucleic acids, vectors and recombinant cells and the nucleic acids, vectors and recombinant cells do not require the polypeptides.

Groups I and Groups IV or V are patentably distinct because the polypeptide can be used to isolate antibodies while administering a recombinant cells or antibody can be used to treat cancer. The protocols and reagents required to use polypeptides are materially distinct and separate than those required to use recombinant cells. The polypeptides do not require the recombinant cells or antibodies and the recombinant cells or antibodies do not require the polypeptides.

Groups I and VI or VII are patentably distinct because the polypeptide can be used to isolate antibodies while assaying a sample can be used to detect cancer. The protocols and reagents required to use polypeptides are materially distinct and separate than those required to detect protein complexes or T cells or to use transfected cells *in vitro*. The polypeptides do not require the method of detecting cancer and the method of detecting cancer does not require the polypeptides.

Groups II and III are patentably distinct because the CTL can be used in cytotoxicity assays *in vitro* while the nucleic acids, vectors and recombinant cells can be used to treat cancer. The protocols and reagents required to use CTL are materially distinct and separate than those required to use nucleic acids and vectors. The CTL do not require the nucleic acids, vectors and recombinant cells and the nucleic acids, vectors and recombinant cells do not require the CTL.

The recombinant cells require the consideration of transfection and expression of functional protein which is not required for the CTL.

Groups II and IV or V are patentably distinct because the CTL can be used in cytotoxicity assays *in vitro* while administering a recombinant cells or antibody can be used to treat cancer. The protocols and reagents required to use CTL are materially distinct and separate than those required to use recombinant cells or antibodies to treat cancer. The CTL do not require the recombinant cells or antibodies and the recombinant cells or antibodies do not require the CTL.

Groups II and VI or VII are patentably distinct because CTL can be used in cytotoxicity assays *in vitro* while assaying a sample is used to detect cancer. The protocols and reagents required to use CTL are materially distinct and separate than those required to detect cancer using recombinant cells or antibodies. The CTL do not require the method of detecting cancer and the method of detecting cancer does not require the CTL.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the recombinant cells can be practiced with antibodies or nucleic acids. In addition, the recombinant cells can be used to make protein.

Groups III and V are patentably distinct because the nucleic acids, vectors and recombinant cells can be used to make proteins while the method of using antibodies can be used

to treat cancer. The protocols and reagents required to use the nucleic acids, vectors and recombinant cells are materially distinct and separate than those required to use antibodies. The nucleic acids, vectors and recombinant cells do not require the antibodies and the antibodies do not require the nucleic acids, vectors and recombinant cells.

Groups III and VI or VII are patentably distinct because the nucleic acids, vectors and recombinant cells can be used to make protein while assaying a sample is used to detect cancer. The protocols and reagents required for nucleic acids, vectors and recombinant cells are materially distinct and separate than those required to detect cancer. The nucleic acids, vectors and recombinant cells do not require the method of detecting cancer and the method of detecting cancer does not require the nucleic acids, vectors and recombinant cells.

Group IV and V are patentably distinct. The method of stimulating T-helper cell proliferation using a recombinant cell has a different mode of operation than stimulating T helper cells using antibodies. The method of using recombinant cells require materially distinct and separate protocols than those required to use antibodies. The method of using recombinant cells does not require the antibodies and the method of using the antibodies does not require the recombinant cells.

Groups IV or V and VI or VII are patentably distinct because the method of administering recombinant cells can be used to treat cancer while the method of assaying a sample is used to detect cancer. The protocols and reagents required to treat cancer are materially distinct and separate than those required to detect cancer. The method of treating cancer does not require the

method of detecting cancer and the method of detecting cancer does not require the method of treating cancer.

Groups VI and VII are patentably distinct. The method of detecting cancer by assaying protein complexes or T helper cells are performed by different modes of operation. Assaying protein complexes or T cell which recognize protein complexes require materially distinct and separate protocols and reagents than a method of assaying using transfected cells. The method of assaying protein complexes or T helper cells does not require the method of using transfected cells and the method of using transfected cells does not require the method of assaying protein complexes or T helper cells.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classifications, the search required and the separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: screening cancer by detecting (a) protein complexes and (b) T cells specific for protein complexes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42, 43 and 47-52 are generic. If applicants elect Group XII, applicants should elect one of the single disclosed species. If applicants elect Group XII, claims 53 and 54 will only be examined if applicants elect the species of T cells.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson

Deborah Clark

DEBORAH J. CLARK
PATENT EXAMINER